K071784

JUL 25 2007

510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Associate Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@dpyus.jnj.com
DATE PREPARED:	June 22, 2007
PROPRIETARY NAME:	DePuy Pinnacle® with Gription™ Acetabular Cups
COMMON NAME:	Acetabular Cup with Porous Coating
CLASSIFICATION:	Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
DEVICE PRODUCT CODE:	87 LPH
SUBSTANTIALLY EQUIVALENT DEVICES:	Pinnacle® Acetabular System, K001534 (June 12, 2000) Pinnacle® Revision System, K033338 (January 8, 2004)

DEVICE DESCRIPTION:

The Pinnacle Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from ultra high molecular weight polyetheylene (UHMWPE) or high-carbon cobalt chrome (CrCoMo), both of which lock into the outer shell. The liner component articulates with a femoral head of an appropriate diameter. The subject acetabular cups are coated with a new proprietary titanium porous coating, Gription™.

INDICATIONS AND INTENDED USE:

Indications:

Pinnacle® Acetabular Cups are indicated for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Porous-coated Pinnacle® Acetabular Cups are indicated for cementless application.

Intended Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Pinnacle Porous Coated Acetabular Cup total hip components are indicated for cementless use with fixation provided by biological tissue ingrowth into the porous coating.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Pinnacle® with Gription™ Acetabular Cups have the following similarities to the Pinnacle® Acetabular Cups (with Porocoat®) that were cleared in K001534 and K033338:

- Identical intended use and indications for use
- Identical material
- Identical design
- Identical sterilization and packaging
- Identical method of manufacturing

The Pinnacle® with Gription™ Acetabular Cups are substantially equivalent to the Pinnacle® Acetabular Cups (with Porocoat®) based on similarities in intended use, indications for use, material, design, sterilization, packaging and method of manufacturing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Affairs Associate
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K071784
Trade/Device Name: DePuy Pinnacle® with Gription™ Acetabular Cups
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: June 29, 2007
Received: July 2, 2007

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): K071784

Device Name: **DePuy Pinnacle® with Gription™ Acetabular Cups**

Indications for Use:

Total Hip Arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Pinnacle® Acetabular Cups are indicated for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Porous-coated Pinnacle® Acetabular Cups are indicated for cementless application.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071784